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10/801,550

03/17/2004

Stephen L. Dellaporta

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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/801,550

Applicant(s)

DELLAPORTA ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-91 is/are pending in the application.
- 4a) Of the above claim(s) 55-66, 73 and 79-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-72 and 74-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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***Restriction/Election***

Applicant's election of Group III and Species A (male-preferred promoters) in the reply filed on 11 October 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 55-91 are pending. Claims 67-72 and 74-78, corresponding to elected Group III and elected Species A, are examined. Claims 55-66, 73 and 79-91, drawn to non-elected inventions, are withdrawn.

***Specification Objection***

The preliminary amendment to page 1 of the specification, submitted 17 March 2004, is objected to for failing to recite the issued patent number corresponding to the parent application. Furthermore, the amendment of 17 March 2004 did not direct the deletion of the continuing data paragraph originally recited on page 1 of the specification. All specification amendments should comply with 37 CFR 1.121(b).

***Indefiniteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-72 and 74-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 67 and 76 and dependents are indefinite in their recitation in part a) of "promoter operably linked to a suicide gene" which is confusing, since "gene" is understood to comprise a promoter and a coding region. Thus, it appears that two promoters are ligated to a single coding region. If that was not intended, replacement of "suicide gene" with --suicide coding region-- would obviate this rejection. Claim 77 is similarly rejected.

Claim 74 is indefinite in its recitation of "the suicide coding region" which lacks antecedent basis in claim 67 as filed. Amending claim 67 as suggested above, claim 74 would overcome this rejection.

Claim 74 is further indefinite in its recitation of "codes for a gene" which is confusing, since genes are not encoded by other genes. Replacement of "codes for" with ---is from--- would obviate this rejection.

Claim 75 is indefinite in its recitation of "codes for... herbicide resistance..." since genes encode proteins, not traits. Replacement of "codes for" with --confers-- would obviate this rejection.

Claim 75 is indefinite in its recitation of "altered nutrition". It is unclear whether "altered nutrition" refers to nutritional content when consumed by animals, or ability of the plant to extract nutrients from its environment.

Claims 67 and 76 are indefinite in their recitation of "propagating said transformed plant cell through meiosis", as it is unclear whether the initial cell is one which normally undergoes meiosis, i.e. a cell from which gametes are directly descended; or whether it is intended that the transformed plant cell is a somatic cell

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which is regenerated into a whole plant, which plant produces cells which undergo meiosis in the reproductive phase of the plant.

Claim 76 is indefinite in its recitation in part a) of "encoding a transposon" which is confusing, since transposons comprise nucleic acid and are not encoded by nucleic acid. Replacement of "encoding a transposon" with ---comprising a transposon--- would obviate this rejection.

***Enablement***

Claims 67-72 and 74-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to the use of any transposon to enrich transposon dispersion in any plant species, wherein said transposons may not contain active transposase-encoding genes (claim 67), and wherein a multitude of agronomic traits including "altered nutrition" and "nitrogen fixation" are conferred by a multitude of single genes of interest of any sequence (claim 75). Claims 67 and 76 are also broadly drawn to the use of any "male gamete-specific promoter" including tapetum-specific promoters, anther-specific promoters, microspore-specific promoters, and pollen-specific promoters (the latter as recited in claim 72). For those claims which do specify the presence of a transposase gene, namely claims 68 and 76 and dependents, a multitude of non-exemplified promoters are contemplated, including tissue-specific, constitutive,

inducible, and developmentally regulated promoters active in a variety of cell and tissue types of a variety of ages.

In contrast, the specification does not demonstrate any transformed plants containing transposon constructs operably linked to male sterility constructs, and does not evaluate the dispersion of transposition events in any plant or population of plants. The specification does suggest the use of the Ac/Ds system derived from maize, and also suggests the use of pollen-specific promoters operably linked to the suicide coding sequence (see the portions of the specification cited below).

Furthermore, no attempt was made to identify or isolate a multitude of genes conferring plant nitrogen fixation ability, or altered plant nutrition, wherein said genes have not previously been identified or isolated in the art. Nitrogen fixation is accomplished by microbes in symbiotic association with a plant, rather than the plant itself. The genetic basis for "plant nutrition", as reflected by the ability to absorb nutrients from the growth medium, has heretofore been undescribed, and would appear to be based upon a multitude of quantitatively inherited genes, rather than a single gene as claimed.

Dispersion of transposition events is unpredictable, given the tendency for localized transposition, the lack of control over plant developmental stage where transposition occurs, the tendency for non-independent transposition events, and the lack of utility of permanent gene insertions; wherein the use of pollen-specific promoters operably linked to the suicide coding sequence, the use of floral meristem-preferred promoters operably linked to the transposase-encoding sequence, and the requirement

for a transposase-encoding sequence for subsequent remobilization of the transposon, are suggested albeit non-evaluated solutions to the above problems (see, e.g., the instant specification, page 34, lines 9-20; page 35, line 24 through page 36, line 24; page 39, lines 17-18 and 29-31; page 40, lines 15-16 and 24-26; page 41, lines 3-8 and 14-16; page 42, lines 19-24 and 29-33; page 43, lines 8-9 and 24-30).

Moreover, transposition-mediated marker gene movement (including excision) is slow and inefficient. See, e.g., Ebinuma et al (1997), who teach that six months was required for transposon-mediated oncogene excision, and that only 0.032% marker-free plants were obtained (see, e.g., page 2120, column 2, penultimate paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to evaluate the ability of a multitude of non-exemplified transposons to enrich dispersion of transposition events in a population of a multitude of non-exemplified plant species, when operably linked to constructs comprising a multitude of male-gamete-specific promoters operably linked to suicide coding regions, particularly in the absence of a transposase gene, or in the absence of a floral-specific promoter operably linked to said transposase gene. Undue experimentation would have also been required to identify and isolate a multitude of non-exemplified genes conferring nitrogen fixation ability or altered plant nutrition to plants; and to evaluate the ability of a multitude of these non-exemplified genes to confer the desired phenotypes in plants transformed therewith.

***Written Description***

Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to nucleic acid constructs comprising a multitude of non-exemplified genes conferring to plants nitrogen fixation ability or altered plant nutrition. In contrast, the specification provides no guidance for any gene conferring either of these traits. Furthermore, no attempt was made to identify or isolate a multitude of genes conferring plant nitrogen fixation ability, or altered plant nutrition, wherein said genes have not previously been identified or isolated in the art. Nitrogen fixation is accomplished by microbes in symbiotic association with a plant, rather than the plant itself.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed



genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

***Anticipation***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 67, 69-71 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/38323 (BIOCEM); equivalent to US 7,112,719 (Perez et al).

The claims are drawn to a method for transforming a plant cell with a construct comprising a male gamete-specific promoter operably linked to a suicide gene, wherein said nucleic acid construct is linked to a transposable element and comprises a gene of interest including herbicide resistance or insecticide resistance, wherein the cells are propagated through meiosis and progeny are recovered.

BIOCEM teaches a method of plant transformation with a construct comprising a male-gamete-specific A9 promoter operably linked to a glucanase suicide coding sequence, wherein said nucleic acid construct is linked to the maize Ds transposable element and comprises a gene of interest conferring resistance to the herbicide basta, wherein cells are propagated through meiosis (via sexual crossing to plants containing a transposase-encoding construct) and progeny are recovered and analyzed (see, e.g., page 10, lines 11-26; page 13, lines 14-17; page 18, lines 9-10; page 19, lines 11-21;

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pages 27-29; page 33 through page 34, line 19; pages 40-41; see also the following columns of the corresponding US patent: column 7, lines 5-9; column 9, lines 17-21 and 55-67; column 13, line 15 through column 14, line 15; column 15, line 41 through column 16, line 33; column 18, line 59 through column 19, line 47).

**Obviousness**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67-72 and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/38323 (BIOCEM) in view of each of WO 96/26283 (PLANT GENETIC SYSTEMS; MICHIELS et al) and WO 93/25695 (PLANT GENETIC SYSTEMS, WILLIAMS et al).

The claims are broadly drawn to methods of plant transformation with a nucleic acid construct comprising a transposon and a pollen-specific promoter operably linked to a suicide coding sequence including a barnase-encoding sequence, said nucleic acid construct operably linked to a transposase-encoding construct and another gene of interest; wherein transformed plants are propagated through meiosis and progeny recovered.

BIOCEM teaches a method for plant transformation with a construct comprising a male gamete-specific promoter operably linked to a suicide coding sequence, said nucleic acid construct operably linked to a maize Ds transposon, and also teaches the crossing of plants transformed with said construct by plants containing a transposase-encoding construct, wherein plants containing both the transposase-encoding construct and the transposon are obtained, as discussed above.

BIOCEM does not teach the use of the subset of male gamete-specific promoters known as pollen-specific promoters, the particular suicide coding sequence encoding barnase, or the use of co-transformation with a transposase-encoding sequence.

PLANT GENETIC SYSTEMS (Michiels et al) teaches plant cells and plants transformed with a vector comprising a male-sterility locus comprising a DNA construct comprising the tapetum- or pollen-specific PE1 or CA55 promoters ligated to a barnase gene, linked to the *bar* gene, and progeny plants which are hemizygous for the construct (see, e.g., page 2, line 31 to page 3, line 6; page 11, line 9 to page 12, line 6;

page 13, lines 1-11; page 16, lines 3-6; page 19, lines 4-16; page 24, lines 3-5 and 16-21; page 26, lines 7-11; page 28, lines 3-6; page 29, Table 1; page 30, Table 2).

PLANT GENETIC SYSTEMS (WILLIAMS et al) teaches plant cells and plants transformed with a vector comprising a male-sterility locus comprising a DNA construct comprising the tapetum- or pollen-specific PTA29 or Zm13 promoters ligated to a barnase gene, linked to the *bar* gene, and progeny plants which are hemizygous for the construct; and also teaches plant cells and plants transformed with a vector comprising a maintainer locus comprising a DNA construct comprising a pollen lethality gene comprising the tapetum- or pollen-specific PTA29 or Zm13 promoters ligated to a barnase gene, linked to the *bar* gene, wherein said pollen lethality locus is hemizygotic for the barnase gene; and also teach a method for eliminating male transmission of the pollen lethality transgene when crossed with another plant, due to the loss of the transgene at meiosis (see, e.g., page 2, bottom paragraph; page 4, bottom paragraph; page 5, lines 5-7; page 6, top paragraph and bottom two paragraphs; pages 7-8; page 11, top paragraph; page 12, bottom paragraph; page 13; page 14, top and bottom paragraphs; page 15, top two paragraphs; page 22, middle paragraph; page 23, top paragraph; page 24, middle paragraph, first three sentences; page 25, first full paragraph; pages 30-32; page 33, bottom paragraph through page 35; page 38, bottom paragraph through page 40, top two paragraphs; page 41, bottom half; page 42, bottom paragraph; page 43; page 44, top two paragraphs).

It would have been obvious to one of ordinary skill in the art to utilize the method of transposon-mediated plant transformation taught by BIOCEM, and to modify that

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method by incorporating the particular pollen-specific promoters and suicide coding regions taught by each of PLANT GENETIC SYSTEMS, given the recognition by the artisan of ordinary skill that each would have continued to function in its known and expected manner, in the absence of evidence to the contrary. Furthermore, given the teaching of BIOCEM of the advantages of obtaining plants with both a transposase-encoding construct and a transposon-comprising construct, it would have been obvious to co-transform a plant with both constructs.

Claims 67-71 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoder et al (US 5,482,852) in view of Oliver et al (US 5,977,441).

Yoder et al teach a method of plant transformation with nucleic acid constructs comprising a Ds transposon, a gene conferring an agronomic trait, and a gene of interest conferring insect resistance, optionally together with a gene encoding a transposase, wherein a selectable marker gene may occur within the ends of the transposon, and wherein plants are propagated through meiosis via sexual crossing (see, e.g., column 4, lines 24-67; column 10, lines 3-47 and 61-67; column 11, lines 1-27; column 14, line 51 through column 16; column 22, lines 12-67; claims 1-9).

Yoder et al do not teach a method wherein the agronomic trait is male sterility.

Oliver et al teach a method of plant transformation with a construct comprising sequences which recognize a transposase (i.e. transposon sequences), a gene encoding a transposase, and a gene conferring an agronomic trait like male sterility or insect resistance, and wherein the male sterility gene may comprise a promoter active

in pollen development, and wherein another gene of interest may confer herbicide resistance (see, e.g., column 5, lines 34-36; column 6, lines 22-27; claims 1-2).

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with a transposon operably linked to a gene conferring an agronomic trait as taught by Yoder et al, and to modify that method by incorporating male sterility as the agronomic trait, as taught and suggested by Oliver.

Claims 72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoder et al (US 5,482,852) in view of Oliver et al (US 5,977,441) as applied to claims 67-71 and 75-78 above, and further in view of each of WO 96/26283 (PLANT GENETIC SYSTEMS; MICHIELS et al) and WO 93/25695 (PLANT GENETIC SYSTEMS, WILLIAMS et al).

Yoder et al taken with Oliver et al teach a method for plant transformation with a construct comprising a transposon and conferring male sterility as discussed above, but do not teach the use of a pollen-specific promoter or a barnase-encoding sequence as the suicide coding sequence.

Each of PLANT GENETIC SYSTEMS teaches such a promoter and coding sequence, as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with a construct comprising a transposon and conferring male sterility as taught by Yoder et al taken with Oliver et al, and to modify that method by incorporating the pollen-specific promoters and barnase-encoding sequences taught by each of PLANT GENETIC SYSTEMS, given the recognition by those of ordinary skill in

the art that choice of available male sterility promoter and coding sequence would have been the optimization of process parameters.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 24, 2006

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180

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